SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1. Purchase Authority: Public Law 92-218 as amended

2. **Request For Proposal (RFP) Number:**	3. **Issue Date:**	4. **Just In Time:**	5. **Set Aside:**
NIH-NIAMS-06-01	JAN. 10, 2006	[ ] NO **[X]** YES See Part IV, Section L	[ ] NO **[X]** YES See Part IV Section L

6. TITLE: ASSESSMENT AND ASSISTANCE FOR NIAMS CLINICAL STUDIES

7. ISSUED BY:	8. SUBMIT OFFERS TO:
BDR\NIAMS Contracts Branch Office of Acquisitions, Division of Extramural Affairs National Heart, Lung and Blood Institute, NIH One Democracy Plaza 6701 Democracy Blvd., Suite 800, MSC 4872 Bethesda, Maryland 20892-4872 Telephone: 301-594-2543 FAX: 301-480-5996	See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.

9. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1 until **4pm local time on February 28, 2006**. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043."

Proposal Intent Response Sheet, Attachment 2 is due January 26, 2006.

10. THIS SOLICITATION REQUIRES DELIVERY OF PROPOSALS TO THE OFFICIAL POINT OF RECEIPT FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY AS STATED IN ATTACHMENT 1. IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH SUBPARAGRAPH (c)(3) OF HHSAR CLAUSE 352.215-70, ENTITLED, "LATE PROPOSALS, AND REVISIONS" LOCATED IN SECTION L.1. OF THIS SOLICITATION.

11. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. (http://www.ccr.gov)

12. FOR INFORMATION CALL OR EMAIL: Lisa A. Hill
PHONE: 301-594-2543; Email Address: hilll1@mail.nih.gov
COLLECT CALLS WILL NOT BE ACCEPTED.

13. Table of Contents on following page.

Lisa A. Hill
Contracting Officer
BDR\NIAMS Contracts Branch
Office of Acquisitions, Division of Extramural Affairs
National Heart, Lung and Blood Institute, NIH

13. DETAILED TABLE OF RFP CONTENTS

PART I - THE SCHEDULE

THE CONTRACT SCHEDULE SET FORTH IN SECTIONS B THROUGH H, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS **NOT** AN EXACT REPRESENTATION OF THE PROPOSED CONTRACT DOCUMENT. CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (I.E., THOSE RELATING TO THE ORGANIZATIONAL STRUCTURE [E.G., NON-PROFIT, COMMERCIAL] AND SPECIFIC COST AUTHORIZATIONS UNIQUE TO THE OFFEROR'S PROPOSAL AND REQUIRING CONTRACTING OFFICER PRIOR APPROVAL) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. HOWEVER, THE ENCLOSED CONTRACT SCHEDULE PROVIDES ALL THE NECESSARY INFORMATION FOR THE OFFEROR TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The Contractor shall perform technical support for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) clinical research activities (clinical trials, epidemiological studies, registries, observational studies, etc.) Areas of research include arthritis, skin diseases, musculoskeletal diseases, osteoporosis, and other diseases/conditions that are in the NIAMS mission.

ARTICLE B.2. PRICES/COSTS

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

GENERAL INFORMATION

1. Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, to perform technical support for NIAMS clinical research activities (clinical trials, epidemiological studies, registries, observational studies, etc.) Areas of research include arthritis, skin diseases, musculoskeletal diseases, osteoporosis, and other diseases/conditions that are in the NIAMS mission. It is anticipated that technical support will entail such things as:

    - providing logistical and executive secretarial support for Data Safety and Monitoring Boards (DSMBs and OSMBs), Scientific Advisory Committees and Steering Committees (approximately 45% of effort);
    - data quality assurance/quality control of clinical studies (approximately 10% of effort);
    - assistance in the conduct of clinical trials (approximately 5% of effort);
    - prepare OMB clearance documents (approximately 3% of effort);
    - guidance on data safety and monitoring plans including guidance on protocol/manual of operations (MOOP) development (approximately 10% of effort);
    - training materials related to the conduct of clinical trials (approximately 2% of effort);
    - consultation with program staff on policies and procedures related to clinical studies (approximately 5% of effort);
    - biostatistical support (approximately 4% of effort);
    - providing support for data management resources and services for clinical studies including: recruitment strategy review and consultation; review of statistical plans and analysis of approaches to studies (approximately 5% of effort);
    - development and maintenance of on-line tools including Tracking Tool Database; Secure

Website for DSMB and other meetings information; and Clinical Studies Database (approximately 6% of effort)

- maintain and monitor Serious Adverse Events (SAE) and Adverse Events (AE) reports for selected studies (approximately 5% of effort).

2. NIAMS conducts clinical research through various mechanisms: grants, cooperative agreements, and contracts. These research activities include clinical studies (observational, epidemiological, and longitudinal studies as well as Phase I, II, and III clinical trials). NIAMS is currently supporting approximately 273 clinical studies and 60 clinical trials ranging in size from 10 to 1,500 participants as well as several large scale (500 – 5,000 participants) observational studies. The Contractor may be asked to provide assistance, and assessment, or consultation to any of the NIAMS funded clinical studies/trials/registries/repositories.

DESCRIPTION OF PERSONNEL AND RELATED DUTIES

1. A Project Director who shall serve as the principal point of contact with the Government and oversee the following activities:

   a. Follow a mutually acceptable standardized plan and policies and procedures for performance of assistance or assessment visits, and finalize and modify the process/procedures, as needed;

   b. mail, telephone, and on-site assistance, assessments or consultations;

   c. assist with the development of training and orientation presentations for members of committees and boards and for training of investigators on the conduct of clinical trials;

   d. provide logistical and executive secretarial support for Data Safety and Monitoring Board (DSMB, OSMB, Scientific Advisory Committees and Contract Steering Committees) activities;

   e. be available for meetings with the Project Officer on a weekly basis for the first three months of the contract and bimonthly thereafter. In addition, other meetings will take place on an as needed basis to address special topics. The meetings will take place at the NIH, Bethesda, Maryland. The Project Director shall be available for the meetings within 2 hours notice.

   f. prepare reports and plans, as requested;

   g. monitor contract progress;

   h. provide deliverables, as specified; and

   i. maintain budget control.

2. A Project Coordinator for the period of performance of this contract, who shall coordinate activities in the areas listed above.

3. A Statistician to provide assistance as follows:

   a. review and provide recommendations to NIAMS on grant and contract initiatives in areas such as statistical design, sample size calculations, statistical plan, methodology, randomization procedures, etc.;

   b. advise Program Directors on existing NIAMS-funded clinical trials in areas such as the statistical plan/methodology; and

   c. provide an additional, unbiased, opinion on DSMB statistical activities.

4. Support staff for the period of performance of this contract.

5. Consultants who will serve on Data Safety and Monitoring Boards for Phase III trials or those clinical trials that have high risk or public health importance.

[Note to Offerors: The Offeror shall provide a list of the appropriate expertise, but no names of individual consultants or letters of commitment are required.]

6. On an as needed basis, consultants who would participate in on-site assessments (approximately 10 trials per year). Consultants must be professionals of the appropriate specialty for which the clinical trial is being conducted.

WORK AREAS *(This section describes the individual work areas.)*

1. **WORK AREA 1: Administer Contract**

The Contractor shall develop, implement and maintain a project management and planning process so that both the NIAMS personnel and the Contractor can monitor and manage activities in the Work Areas.

a. The Contractor shall perform overall contract management.

b. The Contractor shall ensure that all work is performed on time and within budget.

c. The Contractor shall draft an annual Performance and Operating Plan that covers each work area of the contract. This is for the management of the overall contract. The annual Performance Plan shall address accomplishing the requirements of the contract and focus on quality, timeliness, and cost-control. The first annual Performance Plan shall be largely based on the proposal; the actual operating version of this Plan shall be due within 1 month of contract award.

Subsequent year plans shall be included as part of the annual report. The Plan shall define and describe the projects to be performed, the methods for accomplishing these projects, and allocation of specific personnel, staff hours, and costs per work area. The Contractor shall also provide a labor and cost estimate, and milestones for specific projects as requested by the Project Officer. The Project Officer expects to provide comments and approvals on the Plan within 30 days of submission.

d. The Contractor shall submit reports listed under REPORTING REQUIREMENTS in the quantities and in accordance with the schedules specified therein.

e. The Contractor shall also provide an accounting of costs of major projects (over $15,000 for DSMBs or $5,000 for any other project). This information shall be provided when the Contractor reaches one-half of the estimated project costs (either hours or dollars, whichever occurs first) and when the projects are completed. If the halfway point in costs is reached relatively early, the Contractor shall address the reasons for this and suggest ways to modify the work, if necessary.

f. In order to ensure smooth operations, the Contractor shall be in contact with the Project Officer almost daily via e-mail, the phone, and/or the facsimile machine, and regularly via meetings held at NIH: weekly for the first 3 months and, thereafter, biweekly. The Contractor should also expect to have regular contact with other NIAMS staff, particularly, Extramural Program Clinical Coordinator and Program Directors, in carrying out such tasks as consultation, DSMB assistance, as well as clinical study assessments and assistance. Prior to award, the NIAMS will establish procedures for delegating authority to NIAMS professional staff for the purpose of assigning work under this contract.

g. The Contractor shall plan and participate in information exchange meetings between the Contractor staff and NIAMS staff at least four times per year to coordinate activities between the two offices; discuss needs, opportunities, and trends; and review future collaborations.

These quarterly meetings will alternate between the Contractor's offices and the NIH. The first such meeting shall take place within 2 weeks of contract award and will focus on start-up plans including transition and phase-in procedures (see Work Area 8).

h. The Contractor shall establish individual e-mail addresses for all assigned staff. The Contractor shall ensure that electronic requests are responded to within 8 hours or less. In addition, at a minimum, the Project Director, the Project Coordinator, and research associates must have Internet access to search, read, and retrieve information from Internet sources.

2. **WORK AREA 2: Development and/or revision of Policies regarding Conduct and Oversight of Clinical Studies/Trials**

The Contractor shall keep up-to-date, and revise, as needed, NIAMS guidelines for conducting clinical studies/trials. Current NIAMS Guidance include: "Guidelines for Quality Assurance and Data Integrity in NIAMS Clinical Trials," "Developing a Manual of Operations and Procedures," "Generic Monitoring Plan for Trials Requiring a Safety Officer," "Generic Monitoring Plans for Trials Requiring a Data Safety and Monitoring Board," "Guidelines for Investigator-Initiated Clinical Trials - NIAMS," "Data and Safety Monitoring Guidelines for Investigator-Initiated Clinical Trials,""Guidelines for Sample Sharing Policy Development".

a. The Contractor shall provide technical and administrative assistance for interpretation and implementation of the NIAMS guidelines for specific clinical studies/trials.

[Note to Offerors: The proposal should include a discussion of the criteria to be selected as standards for maintaining high quality clinical studies/trials; their applicability to ongoing or new clinical trials; and modifications needed according to the type and size of the clinical trial.]

b. The Contractor shall provide consultation with NIAMS program staff on policies and procedures (e.g, interpretation of new NIH/FDA policies, how to handle protocol violations, unblinding issues) related to clinical studies/trials on an as needed basis.

[Note to Offerors: The NIAMS anticipates that during the duration of this contract there will be many new policies and regulations regarding patient safety and confidentiality, human subjects, and other clinical study/trial issues. In order to be kept current the NIAMS may request assistance in interpreting and implementing the policies and regulations. It is estimated that there will be approximately 12 policies/procedures consultations per year. Approximately half of them will require a brief written informal response, and the remainder of them may require formal reports ranging from 5-10 pages.]

c. The Contractor shall submit a draft copy of any changes, additions or deletions to the Guidelines based on technical and administrative assistance or consultation on policies or procedures to the NIAMS Project Officer for review and comment. The report shall include a summation of the activities performed and recommended changes, additions, or deletions to the entire document or parts thereof. The Project Officer will obtain any comments from NIAMS staff, and return the draft document and comments to the Contractor within calendar 10 days from the initial date of receipt.

d. Within 15 calendar days following receipt of written comments from the NIAMS Project Officer on the draft report, the Contractor shall submit a final copy of the guidelines or parts thereof to the NIAMS Project Officer and the NIAMS Contracting Officer for review and approval.

e. If no activities are required during a quarter, the Contractor shall identify areas that require updating in the upcoming quarter.

3. **WORK AREA 3: Procedures for Assessing and Assisting Clinical Studies/Trials**

It is anticipated that NIAMS-supported large-scale observational studies and clinical trials may require assistance in interpreting and implementing NIH, NIAMS, or FDA guidelines. In order to assist NIAMS-funded investigators, the Contractor, working together with Program personnel, shall provide assistance to the investigator regarding the studies/trials, and/or conduct assessments of the

studies/trials. Assistance can be described in basic terms as a hands on approach, while an assessment is more of an objective, hands-off, review of a study/trial.

a. NIAMS staff will determine which studies/trials need assistance, assessment, or consultation. NIAMS staff will contact the Principal Investigator (PI) of the study/trial to suggest consultation with the Contractor.

[Note to Offerors: It is estimated that approximately 10 studies/trials per year will require some consultation. The proposal shall describe how and what kind of assistance could be provided to ensure compliance of the NIAMS-supported investigators with the Guidance for the conduct of clinical studies/trials].

b. The Contractor shall conduct assessments and provide assistance to ensure compliance by NIAMS-supported investigators with the existing guidelines, policies, and procedures for the conduct of clinical studies/trials. It is anticipated that all NIAMS-supported trials will be periodically monitored for compliance with existing guidelines, policies, and procedures. This monitoring may be performed by internal trial monitors, NIAMS staff or external monitors.

[Note to Offerors: The offeror should provide a plan for monitoring that addresses clinical trial issues unique to the diseases and conditions that fall within the NIAMS mission (e.g., osteoarthritis, osteoporosis, rheumatiod arthritis, muscular dystrophies, and skin diseases). The proposal shall include: a) description of the type of training and experience the Project Director and his/her staff have in the conduct of clinical study monitoring; b) a description of proposed monitoring procedures; c) what will be covered in the assessments; d) include an outline of the reports to be submitted to NIAMS following these activities; e) how organizational conflicts of interest will be avoided while engaging in assistance and assessment activities, and f) a mitigation plan to address organizational conflict of interest while engaging in assistance and assessment activities.] The proposal shall also include an outline of the reports to be submitted to NIAMS following these activities. The Offeror should explain how it will avoid a conflict of interest while engaging in assistance and assessment activities and provide a mitigation plan addressing conflict of interest.]

c. The Contractor shall submit a fully executed Confidentiality Affidavit for each staff member involved in the assessment to the PI of the site to be assessed prior to the conduct of any assessment. Copies of the affidavits shall also be sent to the NIAMS Project Officer and NIAMS Contracting Officer.

d. The Contractor shall ensure that all study/trial data and results that may be reviewed under this contract are kept confidential and, in all cases, in compliance with the Privacy Act. The Contractor shall not release, publish, or otherwise disclose any trial data and/or information.

e. The Contractor may be required to perform on-site assistance/assessments at clinical or coordinating centers for NIAMS-supported clinical studies/trials. On-site assistance/assessments shall be accomplished by the Contractor alone or in conjunction with the NIAMS Project Officer and/or other NIAMS staff.

[Note to Offerors: The Contractor may be required to perform on-site assistance/assessment at approximately 10 sites per year.]

1. It is estimated that an average of 2 days, including travel, shall be required for each on-site assistance/assessment. Unscheduled site visits may be necessary, with prior approval by the Project Officer, if a site is identified by the NIAMS Project Officer or the Contractor as having significant problems either obtaining and/or managing the data, recruitment or other activities that would hinder the completion of the study/trial. On-site assessments may be accomplished by the Contractor alone or in conjunction with the NIAMS Project Officer and/or other NIAMS staff.

2. The Contractor shall on average review records of a 10% random sample of enrolled patients for data quality assurance/assessment. At the request of the NIAMS Project Officer, the Contractor may also review log books of patients interviewed but ineligible for

entry into the study, and other documents that may assist in the identification of problems/accomplishments.

[Note to Offerors: For proposal preparation the Offeror should estimate that there are 300 subjects in each trial.]

3. The Contractor shall, at the request of the Government and at the time of the on-site assessment, conduct a limited number of additional case reviews where concerns arise regarding, but not limited to, incorrect data entry, patient eligibility, and protocol violations. The Contractor shall obtain prior approval from the NIAMS Project Officer before reviewing additional cases at the visit.

4. The Contractor shall, at the request of the Government and at the time of the on-site assessment, provide training (as outlined in the monitoring procedures) to the PI and/or his/her staff in how to perform an internal audit or other monitoring activities (including review of case report forms and incorrect data entry). The Contractor shall obtain prior approval from the NIAMS Project Officer before training is to begin.

5. The Contractor shall review clinic flow, recruitment and retention plans, case report forms, manual of operations and procedures, and other documents and procedures used in the conduct of clinical research.

6. In trials in which the primary clinical monitor(s) remains masked to treatment assignments (approximately half of the trials), the Contractor may be requested to provide a separate unmasked monitor to visit the site and periodically evaluate the procedures for masking, packaging, dispensing, and accounting for the study medication materials.

7. The Contractor shall be responsible for participating in an exit interview with the NIAMS staff and the PI for the site to discuss the results of the assessment/assistance and provide recommendations on possible next steps.

8. When samples are involved (blood, tissues, etc) an inventory of the samples, including the number of tubes or units and amount of material per tube or unit will be conducted.

9. The Contractor shall submit a draft copy of the written on-site assistance/assessment to the PI for the site visited and to the NIAMS Project Officer for review and comment within 10 calendar days following the conclusion of the assessment/assistance. The reports shall include a summation of the activities performed for the particular assessment and shall contain specific deficiencies noted, if any. The report shall also include conclusions drawn from the assessments performed and recommendations for addressing them, if appropriate. The Project Officer will obtain any comments made by the site PI and return the draft report and comments to the Contractor within 10 calendar days from the initial date of receipt.

10. The Contractor shall submit a final copy of the written on-site assessment to the NIAMS Project Officer for review and approval, within 15 calendar days following receipt of written comments from the NIAMS Project Officer on the draft report. The Contractor shall also submit a final copy of the written assessment to the PI for the site visited.

11. The Contractor shall submit a draft copy of the written mail or telephone assistance/assessment to the PI for the site assessed, and the NIAMS Project Officer for review and comment, within 10 calendar days following the conclusion of the assessment. The reports shall include a summation of the activities performed for the particular assessment and shall contain specific deficiencies noted, if any. The report shall also include conclusions drawn from the assessments performed and recommendations for addressing them, if appropriate. The Project Officer will obtain any comments made by the site PI and return the draft report and comments to the Contractor, within 10 calendar days from the initial date of receipt.

12. The Contractor shall submit a final copy of the written mail or telephone assistance/assessment to the NIAMS Project Officer and the NIAMS Contracting Officer for review and approval, within 15 calendar days following receipt of written comments from the NIAMS Project Officer on the draft report. The Contractor shall also submit a final copy of the written assessment to the PI for the site assessed.

13. The Contractor shall assist the NIAMS Project Officer with preparation of OMB clearance documents. According to required standards for timely submission to the NIH for clearance.

f. Assessments and assistance at participating clinical centers shall include, but not be limited to, review of the following:

1. Data collected are accurate and complete compared to case report form entries, database elements, and the patient medical records;

2. Institutional Review Board (IRB) approval was obtained prior to enrollment of patients and is current;

3. Informed consent forms are complete;

4. Patients satisfied the entry criteria (and did not meet any exclusion criteria) for the study;

5. Data entered into the database for the study agree with data in the patient- specific study records;

6. Documentation exists in the medical records of the patients which validates adverse events reports and outcome measures used in the study; and

7. Instances of withdrawal from the protocol and protocol violations are documented.

g. Assessments/assistance at coordinating centers shall focus on protocol implementation and data management issues including, but not limited to, verifying or assessing the following:

1. Adherence to eligibility criteria;

2. Accuracy of data entry;

3. Security measures for protecting the privacy of the patients;

4. Proper documentation of changes and updates in the database;

5. Adequacy of procedures for monitoring adverse events;

6. Appropriateness of plans for database documentation and archiving; and

7. Assistance with close-out procedures.

4. **WORK AREA 4: Biostatistical Support**

The Contractor shall provide biostatistical support to NIAMS staff who oversee clinical studies/trials. Activities may include:

a. Review and make recommendations to NIAMS in areas such as statistical design, sample size calculations, statistical plan, methodology, and randomization procedures.

b. Review and make recommendations to NIAMS on ongoing NIAMS-funded clinical trials in areas such as statistical significance, power calculations, interim analysis, effect size, subanalysis, outcome measurements, treatment effect, and study design and analysis.

c. Review and make recommendations to NIAMS about DSMB statistical plans, interim analysis, effect size, and other planned statistical discussions. The Contractor may be requested to provide consultation to the study statistician when requested by NIAMS.

d. Performance of activities under this work area will be conducted on an as-needed basis. The Contractor should be able to provide support with quick turn around.

[Note to Offerors: The NIAMS anticipates that up to 10 trials per year will require up to 3 days each of biostatistician review.]

e. The Contractor shall submit a draft copy of the written report to the NIAMS Project Officer for review and comment within 10 calendar days following the conclusion of the statistical support, unless otherwise requested by the Project Officer. The reports shall include recommendations and identify specific deficiencies, if any. The Project Officer will obtain any comments from NIAMS program staff and, if appropriate, the site PI The draft report with comments will be returned to the Contractor within 10 calendar days from the initial date of receipt.

f. The Contractor shall submit a final copy of the written statistical report to the NIAMS Project Officer and the NIAMS Contracting Officer for review and approval within 15 calendar days following receipt of written comments from the NIAMS Project Officer on the draft report.

5. **WORK AREA 5: Training**

With the increase in policies and regulations regarding clinical studies/trials, human subject protection, and other issues related to clinical research, NIAMS wants to ensure that investigators and members of advisory groups are prepared to carry out studies/trials accurately. One way to ensure that investigators are prepared is to have the Contractor assist with development of training modules for use by the NIAMS staff. In order to carry out this activity, the Contractor shall:

a. Assist with developing modules that can be used by NIAMS staff at national meetings (e.g., American College of Rheumatology, American Society for Bone and Mineral Research, North American Spine Society and the American Academy of Dermatology) to train investigators on conducting clinical trials. This modules shall include:

- how a clinical trial should be conducted (good clinical trial practices),
- developing a protocol and a manual of operations,
- appropriate activities for each phase of clinical trials (prerecruitment, recruitment, follow up/adherence, and close-out),
- identification and reporting of Adverse Events and Serious Adverse Events, and
- what type of reporting and oversight are needed.

b. Incorporate training materials from NIAMS, NIH, or FDA documents and other documents relevant to preparing and conducting a clinical research study.

1. The Contractor shall be responsible for working with NIAMS staff to develop generic training modules. In addition, the Contractor shall be responsible for customizing the module(s) for the audience for which training will be provided (i.e., if training is to be at a national organization/association meeting, then materials and examples should be appropriate for that population).

2. Training materials shall be available via electronic copy (e.g., WORD, WordPerfect, PowerPoint) as well as hard copy.

3. The Contractor shall be responsible for developing an evaluation instrument to obtain feedback regarding how to improve the training. The report of the evaluation results should outline next steps, if appropriate.

4. The Contractor shall submit a draft copy of the training materials to the NIAMS Project Officer for review and comment no later than 30 calendar days prior to training. The materials shall include a summary of the training session and topics to be covered, as well as examples, references, and resources to be provided to the audience. The Project Officer may obtain review and recommendations from staff/investigators in the field and return the draft copy and comments to the Contractor within 10 calendar days from the initial date of receipt.

5. The Contractor shall submit a final copy (hard and electronic version) of the training materials to the NIAMS Project Officer for review and approval within 10 calendar days following receipt of written comments from the NIAMS Project Officer on the draft training materials.

6. The Contractor shall submit a draft summary of the results of the evaluation to the Project Officer no later than 15 calendar days after the completion of the training. The summary shall include lessons learned, topics that need further investigation, and recommendations to the NIAMS Project Officer for review and comment.

6. **WORK AREA 6: Data Safety and Monitoring Support**

The Contractor shall provide data safety and monitoring support for NIAMS-funded clinical studies. These activities may vary from providing logistical support (arranging travel and honoraria for Committee members) to serving as the executive secretary of a DSMB/Advisory Committee/Steering Committee or assisting in the development of a data safety and monitoring plan. For the purposes of this section, reference to Committees includes DSMBs/OSMBs and any other Advisory or Steering Committees providing input to NIAMS regarding Clinical studies

[Note to Offerors: The proposal shall describe knowledge of and experience in the participation of data safety and monitoring boards and other advisory to committees. The offeror shall provide a description as to how DSMB support will be implemented, including executive secretarial support and other logistic support.]

a. The Contractor shall review data safety and monitoring plans that have been customized for specific NIAMS-funded clinical studies (including providing recommendations on the use of a safety officer vs. a data safety and monitoring board).

[Note to Offerors: NIAMS anticipates that there will be up to 5 clinical studies per year that will need some assistance in developing/customizing their clinical study monitoring plan. Each activity is expected to require from 8 to 16 hours each. This activity is not expected to include any travel by contractor staff.]

b. Upon completion of review of the data safety and monitoring plan, the Contractor shall submit a copy of the data safety and monitoring plan with recommendations to the NIAMS Project Officer for review and comment within 10 calendar days. The Project Officer will obtain any comments from NIAMS Program Staff and, if appropriate, the site PI. The draft report with comments will be returned to the Contractor, within 10 calendar days from the initial date of receipt.

c. The Contractor shall submit a final copy of their review of the site-specific data safety and monitoring plan, addressing NIAMS or the PI comments. This document shall be forwarded to the NIAMS Project Officer for review and approval within 15 calendar days following receipt of written comments from the NIAMS Project Officer on the draft report.

d. The Contractor shall provide Committee support which includes the following:

1. Executive secretarial support for the Committee including logistical support (scheduling meeting dates and locations, etc.), distributing meeting materials, taking notes, and writing meeting action items and minutes.

   The Contractor shall submit a draft copy of all materials prepared for the Committee to the Project Director/Clinical Coordinator who is responsible for the trial before any materials are sent out. This should be done approximately 1 month prior to the meeting, unless otherwise agreed upon by the Contractor, Program Director/Clinical Coordinator, and the Project Officer. A list of all materials distributed shall be sent to the NIAMS Project Officer at the same time as draft documents are sent out for comment.

2. Draft minutes are to be sent to NIAMS within 10 calendar days of the meeting. A format for the minutes will be agreed upon prior to the first meeting; it is expected that the minutes will be bullets with action items. NIAMS Program Director/Clinical Coordinator will review and approve within 15 calendar days of receipt. Comments are then to be obtained by the Committee members within 15 calendar days. The DSMB meeting minutes shall be finalized no later than 45 calendar days after the meeting. The Contractor is to distribute the minutes to the PI, appropriate NIAMS staff, and Committee members. A copy of all Committee materials shall be sent to the Program Director/Clinical Coordinator, and NIAMS Project Officer once the minutes have been approved and distributed to the members.

3. Travel arrangements for Committee members (travel arrangements, per diem, honorarium, etc.)

*[Note to Offerors: The NIAMS anticipates there will be **30 DSMB and other Committee meetings during year 1, 35 during year 2, and 40 during year 3 and thereafter**. Each Committee will generally have five to seven members. Honorarium will not exceed the Government rate of $250/day. It is expected that there will be one face-to-face meeting and one conference call per year. Travel, per diem and honorarium per Committee member, per trip is projected in the amount of $1,000.]*

[Note to Offerors: The proposal should provide recommendations for establishing standing DSMBs for certain diseases/trials. Both logistical and scientific management of these DSMBs should be described and how this would effect the overall efficiency.]

7. **WORK AREA 7: Development and Maintenance of Databases and Website**

   The Contractor shall support NIAMS in enhancing electronic communication for the management of DSMB and other meeting information, materials and reports and shall design, maintain and revise existing related databases and web pages to incorporate new technology and efficiencies. To accomplish this the contractor shall:

   a. Provide and maintain a website on which DSMB/OSMB and other meeting participants can access study materials and meeting-related information.

   b. Provide and maintain a Clinical Trials Database that will provide access to information and reports that summarize each Program Director's clinical research portfolio characteristics.

   c. Maintain a tracking tool database with up-to-date information needed to efficiently carry out the Executive Secretariate functions associated with DSMBs/OSMBs and other assigned meetings.

8. **WORK AREA 8: Transition Plan And Contract Close Out**

   The Contractor must plan for an orderly transition at both the start and end of the contract. The transition period at the beginning and end of the contract shall be 1 month.

   a. Start-up: NIAMS requires that there be no disruption to services to be continued under this proposed contract. The successor Contractor shall provide the Project Officer with a list of all

the steps and materials needed to carry out the transition and phase in the various requirements of the contract. The successor Contractor shall be responsible for transportation of materials and other costs required for the transition.

b. The Contractor shall perform the following activities at the time of contract expiration:

1. The Contractor shall cooperate fully with the successor Contractor.

2. The Contractor shall participate in meetings and telephone conversations with the Project Officer and the successor Contractor in which current procedures and activities are discussed in detail.

3. The Contractor shall deliver to the successor Contractor the following in accordance with the delivery schedule: all stored publications and materials; all Government-furnished and contractor-acquired equipment; all reference materials; correspondence files and program files; master and camera-ready copies of materials; electronic versions of documents developed under this contract; and Web-related files.

4. The Contractor shall also deliver to the successor Contractor all software programs and data developed or altered in the performance of this contract and for which contract funds were expended. Full documentation pertaining to the programs shall also be provided by the Contractor.

5. The Contractor shall pack all items listed in this section in new boxes of uniform size, label each with a unique number and a general description, and deliver them along with copies of an inventory showing the contents of each box in accordance with the delivery schedule, which will be negotiated at the time the transition plan is requested.

ARTICLE C.2. REPORTING REQUIREMENTS

a. Technical Progress Reports

In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award.

1. Quarterly Progress Reports

These reports shall include individual summary statements of the work performed under each active or completed work assignment during the previous quarter, and shall include the status of any outstanding work assignments and unresolved issues under each. The reporting period shall consist of three full calendar months. The first report shall cover the period consisting of the first full three calendar months of this contract and any fractional part of the initial month. Reports shall be due on or before the 30th calendar day following each reporting period. One copy shall be submitted to the Project Officer and one copy to the Contracting Officer. A Quarterly Report shall not be submitted when the Final Report is due.

2. Annual Progress Reports

The Contractor shall submit an annual report that describes the significant activities and accomplishments that have occurred in the preceding contract year. It will contain an overview followed by sections reporting on each work area. In the final section of the report, the contractor shall analyze the assessment and assistance activities over the year and recommend future directions. The annual report shall cover the period consisting of twelve calendar months. Reports shall be submitted on or before the 30th calendar day following the

end of the reporting period. One copy of the report shall be submitted to the Project Officer and one copy shall be submitted to the Contracting Officer.

3. Annual Performance and Operating Plan

The Contractor shall submit an annual Performance and Operating Plan that covers each work area of the contract. This is for the management of the overall contract. The plan shall address accomplishing the requirements of the contract and focus on quality, timeliness, and cost control. The first annual performance plan is due within one month of contract award. Subsequent submissions of the information required in this report shall be incorporated in the Annual Progress Report. One copy of the report shall be submitted to the Project Officer and one copy shall be submitted to the Contracting Officer.

4. Final Report

This report shall include a summation of activities performed during the entire contract period of performance. It shall also include overall conclusions drawn from the data integrity assessments performed and any recommendations for future assessment of data integrity. The Final Report shall be submitted on or before the last day of the contract performance period. One copy shall be submitted to the Project Officer and one copy to the Contracting Officer.

5. Special Reports

The following documents, addressed in Work Area 2, shall be revised as needed in accordance with the Statement of Work. Only final versions are to be provided to the Contracting Officer:

a. Guidance for Quality Assurance and Data Integrity in NIAMS Clinical Trials
b. Developing a Manual of Operations and Procedures
c. Generic Monitoring Plan for Trials Requiring a Safety Officer
d. Guidance for Investigator-Initiated Clinical Trials
e. Data and Safety Monitoring Guidelines for Investigator-Initiated Clinical Trials

A final version of each training module to be used by the NIAMS for training Data Safety Monitoring Board members and others in the conduct of clinical trials and studies in accordance with Work Area 5 of the Statement of Work shall be provided. One copy of each module shall be submitted to the Project Officer and one copy shall be submitted to the Contracting Officer.

6. Reports shall be submitted in electronic format by email or in the form of a disk. All reports should be prepared in WORD or WordPerfect format. If requested by the Contracting Officer, copies of reports shall be sent to the following addresses:

Project Officer
Extramural Program
National Institute of Arthritis and
Musculoskeletal and Skin Diseases, NIH
One Democracy Plaza
6701 Democracy Blvd., Suite 800, MSC 4872
Bethesda, Maryland 20892-4872

Contracting Officer
BDR/NIAMS Contracts Branch, OA, DEA
National Heart, Lung and Blood Institute
National Institutes of Health
One Democracy Plaza
6701 Democracy Blvd., Suite 800, MSC 4872
Bethesda, Maryland 20892-4872

SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, the Project Officer (see ARTICLE G.1.) is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at the National Institute of Arthritis and Musculoskeletal and Skin Diseases, Bethesda, Maryland. Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause 52.246-5, Inspection of Services - Cost-Reimbursement (April 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this contract shall be from September 1, 2006 through August 31, 2011.

ARTICLE F.2. LEVEL OF EFFORT

a. During the period of performance of this contract, the Contractor shall provide 32,300 direct labor hours. The labor hours exclude vacation, sick leave, and holiday. It is estimated that the labor hours are constituted as specified below and will be expended approximately as follows:

Labor Category	Total Direct Labor Hours
Project Director	1,680
Project Coordinator	6,685
Biostatistician	3,000
Research Associates	8,525
Support Staff	9,410
Computer Specialist	3,000
Total	32,300

b. The Contractor shall have satisfied the requirement herein if not less than 90% nor more than110% of the total direct labor hours specified herein are furnished.

c. In the event fewer hours than the minimum specified number of direct labor hours in the total categories are used by the Contractor in accomplishing the prescribed work and the Government has not invoked its rights under the clause, "Termination (Cost-Reimbursement)," FAR 52.249-6, incorporated in this contract, these parties agree that the fee will be adjusted based solely upon the quantity of hours by which the number of direct labor hours furnished is less than the number of direct labor hours specified in this ARTICLE. The resulting adjustment shall be evidenced by a contract modification.

ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with **Alternate I** (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

Any contract awarded from this RFP will contain the following:

ARTICLE G.1. PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

[To be specified prior to award]

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

[The Contracting Officer hereby delegates the Project Officer as the Contracting Officer's authorized representative responsible for signing software license agreements issued as a result of this contract.]

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in this contract, the following individual(s) is/are considered to be essential to the work being performed hereunder:

NAME	TITLE

[To be specified prior to award]

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

1. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts NIH(RC)-1 are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

   a. Invoices/financing requests shall be submitted as follows:

      (1) To be considered a "proper" invoice in accordance with FAR 32.9, Prompt Payment, each invoice shall clearly identify the two contract numbers that appear on the face page of the contract as follows:

          HHS Contract No.: HHSN2642006-------
          ADB Contract No.: N01

      (2) An original and two copies to the following designated billing office:

Contracting Officer
BDR/NIAMS Contracts Branch, OA, DEA
National Heart Lung and Blood Institute, NIH
One Democracy Plaza
6701 Democracy Blvd., Suite 800, MSC 4872
Bethesda, MD 20892-4872

b. Inquiries regarding payment of invoices should be directed to the Contracting Officer at (301) 594 -2543.

c. The Contractor agrees to provide with each invoice/financing request a detailed breakdown of the direct labor/ personnel costs and shall include: (1) a list of the individuals by name; (2) their title position under the contract; (3) the number of hours/percent of effort worked during the current period and the cumulative over the life of the contract; and (4) amount claimed for each individual for the current period as well as the cumulative since the inception of the contract.

d. The following is a listing of expenditure categories to be reported:

1) Direct Labor *(List individuals by name, title/position, level of effort and amount claimed)*
2) Fringe Benefits *(Cite base, rate and amount)*
3) Consultants *(Identify the total amount claimed for each individual below)*
4) Subcontracts *(Identify subcontractors by name and attach subcontractor invoices)*
5) Materials and Supplies
6) Accountable Personal Property/Equipment *(When billing for equipment, the form "Report of Government Owned, Contractor Held Property" must accompany the invoice)*
7) Travel *(Indicate names of travelers, purpose of trip, and costs being billed, i.e., airfare, per diem, ground transportation, etc. for each of the travel categories listed below)*
8) Other Direct Costs *(If reporting costs over $1,000, a separate breakdown of costs included in this category must be provided)*
9) Total Direct Costs
10) Indirect Costs
11) G & A Expense
12) Total Costs

e. The Contractor shall include the following certification on every invoice including costs incurred with Fiscal Year funds subject to the salary rate limitation provisions as specified in ARTICLE H.4. of this contract. For billing purposes, certified invoices are required for the billing period which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with Public Laws as stated in ARTICLE H.4. of the above referenced contract."

ARTICLE G.4. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7(d)(2), "Allowable Cost and Payment" incorporated by reference in this contract in Part II, Section I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Contracts Management
National Institutes of Health
6100 Building, Room 6B05
6100 EXECUTIVE BLVD MSC 7540
BETHESDA MD 20892-7540

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.5. GOVERNMENT PROPERTY

If this RFP may result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the DHHS Publication (OS) 686, entitled, **Contractor's Guide for Control of Government Property**, (1990), which can be found at: http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm.

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluations will be prepared annually to coincide with the anniversary date of the contract.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://oamp.od.nih.gov/OD/CPS/cps.asp

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

ARTICLE H.2. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

a. Pursuant to Public Law(s) cited in paragraph b. , below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any

organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[applicable information to be included at award]

ARTICLE H.3. NEEDLE EXCHANGE

a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.4. PRIVACY ACT

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

The Privacy Act System of Records applicable to this project is Number 09-25-026. This document is incorporated into this contract as Attachment ___

ARTICLE H.5. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to the P.L.(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown or the applicable Executive Level for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as "indirect costs" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The per year salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

b. **Public Law No.** **Fiscal Year** **Dollar Amount of Salary Limitation***

[Applicable information to be included at award]

c. Payment of direct salaries is limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred.

* For the period 10/1/04 - 12/30/04, the Executive Level I rate is $175,700. Effective January 1, 2005, the Executive Level I rate increased to $180,100 and will remain at that rate until it is revised. See the web site listed below for the Executive Schedule rates of pay:

FOR FY05 EXECUTIVE LEVEL SALARIES EFFECTIVE JANUARY 1, 2005:
http://www.opm.gov/oca/05tables/html/ex.asp
(NOTE: This site shows the CY 05 rates. For previous years, click on "salaries and wages" and then scroll down to the bottom of the page and click on the year to locate the desired Executive Level salary rates).

ARTICLE H.6. INFORMATION TECHNOLOGY SYSTEMS SECURITY SPECIFICATIONS

The Statement of Work (SOW) requires the Contractor to develop or access Federal automated information systems; therefore, the contractor shall comply with the "DHHS Information Security Program Policy" (http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc) as set forth below. The contractor shall include this provision in any subcontract awarded under this contract.

a. Required IT Systems Security Training

The Contractor shall assure that each employee has completed the NIH Computer Security Awareness Training at http://irtsectraining.nih.gov/ prior to performing any work under this contract.

The Contractor shall maintain a listing by name and title of each individual working under this contract who has completed the NIH required training. Any additional security training completed by contractor staff shall be included on this listing.

b. Rules of Behavior

The Contractor shall comply with the DHHS Rules of Behavior set forth in DHHS Information Security Program Policy Handbook, Appendix G at:
http://intranet.hhs.gov/infosec/docs/policies_guides/ISPPH/PG_ISHbkv2_11_12_2004.pdf; and
the NIH Information Technology General Rules of Behavior at:
http://irm.cit.nih.gov/security/nihitrob.html.

c. Position Sensitivity Designations

(1) The Government has determined that the following position sensitivity designations and associated clearance and investigation requirements apply under this contract:

Level 5C: Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI). Contractor employees assigned to a Level 5C position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or possibly a Limited Background Investigation (LBI).

**** (List applicable Contractor Position Titles here if considered appropriate.) ****

(2) The Contractor shall submit a roster, by name, position and responsibility, of all IT staff working under the contract. The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 days of the effective date of the contract. Any revisions to the Roster as a result of staffing changes shall be submitted within fifteen (15) calendar days of the change. The Contracting Officer shall notify the contractor of the appropriate level of suitability investigations to be performed.

Contractor employees who have had a background investigation conducted by the U.S. Office of Personnel Management (OPM) within the last five years may only require an updated or upgraded investigation.

(3) The Contracting Officer will provide the contractor with a Web site where the contractor may obtain forms needed to complete background investigations. The Contractor shall complete the forms and mail them to:

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

b) Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

(15)**Electronic and Information Technology Accessibility**

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that:

a. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

b. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards.

Further information about Section 508 is available via the Internet at http://www.section508.gov .

(16)**UNIFORM RESOURCE LOCATORS (URLs) IN CONTRACT PROPOSALS**

All proposals must be self-contained within the specific page limitations cited elsewhere in this solicitation. Unless otherwise specified, URLs/Internet addresses shall not be used to provide information necessary to the review because reviewers are under no obligation to review the Internet sites.

(17)**Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).
b) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).
c) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
d) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).
e) Identification of Uncompensated Overtime, FAR Clause 52.237-10, (October 1997).
f) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
g) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. **TECHNICAL PROPOSAL INSTRUCTIONS**

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks. **Also, please make sure to address all NOTES TO OFFERORS outlined in PART I, SECTION C, ARTICLE C.1, Statement of Work.**

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Project Objectives, NIH-1688-1**

The offeror shall insert a completed NIH Form 1688-1, Project Objective, as provided in Section J, Attachments, behind the Title Page of each copy of the proposal, along with the "Government Notice for Handling Proposals." The NIH Form 1688-1 is to be completed as follows:

- For an **Institution of Higher Education:** The form MUST be completed in its entirety.
- For **OTHER** than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank.

The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled, **"INSTRUCTIONS:"**

b) **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless

the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

c) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR/PROJECT DIRECTOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

-The specific items or expertise they will provide.

-Their availability to the project and the amount of time anticipated.

-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (Section M. hereof).

(3) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

(5) **Information Technology Systems Security**

1. **Information Security** is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation.

(a) **Sensitivity and Security Level Designations.**

The Statement of Work (SOW) requires the successful offeror to develop or access a Federal Automated Information System (AIS). Based upon the security guidelines contained in the *Department of Health and Human Services (DHHS) Security Program Policy,* the Government has determined that the following apply:

(1) **Category of Safeguarded Information**

The safeguarded agency information that the successful offeror will develop or access is categorized as:

[ ] Non Sensitive Information
[X] Sensitive Information

(2) **Security Level Designations**

The information that the successful offeror will develop or access is designated as follows:

Confidentiality	Level:	[ ] Low	[X] Moderate	[ ] High
Integrity	Level:	[ ] Low	[X] Moderate	[ ] High
Availability	Level:	[ ] Low	[X] Moderate	[ ] High

Overall Level: [ ] Low [X] Moderate [ ] High

(3) **Position Sensitivity Designations**

Prior to award, the Government will determine the position sensitivity designation for each contractor employee that the successful offeror proposes to work under the contract. For proposal preparation purposes, the following designations apply:

[ ] Level 6C: Sensitive - High Risk (Requires Suitability Determination with a BI). Contractor employees assigned to a Level 6C position are subject to a Background Investigation (BI).

[X] Level 5C: Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI). Contractor employees assigned to a Level 5C position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or possibly a Limited Background Investigation (LBI).

[ ] Level 1C: Non Sensitive (Requires Suitability Determination with an NACI). Contractor employees assigned to a Level 1C position are subject to a National Agency Check and Inquiry Investigation (NACI).

Upon award, the contractor will be required to submit a roster of all IT staff working under the contract. The Government will determine the appropriate level of suitability investigation required for each staff member.

Contractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

(b) **Information Technology (IT) System Security Program**

The offeror's proposal must:

(1) Include a detailed System Security Plan (SSP) of its present and proposed IT systems security program commensurate with the size and complexity of the requirements of the Statement of Work. Offeror's must use the NIH Application/System Security Plan Template available at:

(I) SSP Template (detailed) at http://irm.cit.nih.gov/security/secplantemp.doc

(2) The offeror's SSP shall demonstrate that it complies with the Computer Security Act of 1987; Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems;" and the DHHS Security Program Policy.

(3) Offerors shall include an acknowledgment of its understanding of the security requirements.

(4) Offerors shall provide similar information for any proposed subcontractor developing or accessing an Automated Information System.

(c) **Required Training for IT Systems Security**

DHHS policy requires that contractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each contractor employee has completed the following NIH Computer Security Awareness Training course prior to performing any contract work: http://irtsectraining.nih.gov/. The contractor will be required to maintain a listing of all individuals who have completed this training and submit this listing to the Government.

Additional security training requirements commensurate with the position may be required as defined in OMB Circular A-130 or NIST Special Publication 800-16, "Information Technology Security Training Requirements." These documents provide information about IT security training that may be useful to potential offerors.

(d) **References**

The following documents are electronically accessible:

(1) DHHS Information Security Program Policy:
http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc

(2) DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf

(3) NIH Systems Security Plan Template: http://irm.cit.nih.gov/security/secplantemp.doc

(4) NIH Systems Security Plan Outline:
http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc

(5) NIH Computer Security Awareness Training Course: http://irtsectraining.nih.gov/

(6) NIST Special Publication 800-16, Information Technology Security Training Requirements:
http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf
Appendix A-D:
http://csrc.nist.gov/publications/nistpubs/800-16/AppendixA-D.pdf

(7) NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems:
http://csrc.nist.gov/publications/nistpubs/index.html

(8) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I:
http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V1-final.pdf

(9) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume II:
http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V2-final.pdf

(10) NIST SP 800-64, Security Considerations in the Information System Development Life Cycle:
http://csrc.nist.gov/publications/nistpubs/800-64/NIST-SP800-64.pdf

(11) NIH CIT-Policies, Guidelines and Regulations:
Table 1 - Security Categorization of Federal Information and Information Systems:
http://irm.cit.nih.gov/security/table1.htm
Table 2 - Position Sensitivity Designations for Individuals Accessing Agency Information:
http://irm.cit.nih.gov/security/table2.htm

c. BUSINESS PROPOSAL INSTRUCTIONS

(1) **Basic Cost/Price Information**

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) **Cost and Pricing Data**

[Note: This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.a. of this RFP.]

1. **General Instructions**

A. You must provide the following information on the first page of your pricing proposal:

(1) Solicitation, contract, and/or modification number;
(2) Name and address of offeror;
(3) Name and telephone number of point of contact;
(4) Name of contract administration office (if available);
(5) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
(6) Proposed cost; profit or fee; and total;
(7) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
(8) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
(9) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
(10) Date of submission; and
(11) Name, title and signature of authorized representative.

B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including--

(1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
(2) The nature and amount of any contingencies included in the proposed price.

D. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.

F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.

G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

2. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

A. **Materials and services**. Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.

(1) *Adequate Price Competition*. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).

(2) *All Other*. Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in

support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

B. **Direct Labor**. Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.

C. **Indirect Costs**. Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

D. **Other Costs**. List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

E. **Royalties**. If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

(1) Name and address of licensor.
(2) Date of license agreement.
(3) Patent numbers.
(4) Patent application serial numbers, or other basis on which the royalty is payable.
(5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
(6) Percentage or dollar rate of royalty per unit.
(7) Unit price of contract item.
(8) Number of units.
(9) Total dollar amount of royalties.
(10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).

F. **Facilities Capital Cost of Money**. When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

3. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (Section J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

4. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of

cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

5. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

[NOTE: Data substantiating the costs or prices proposed (i.e. payroll documentation, vendor quotes, invoice price, etc.) shall not be submitted with the initial proposal. This information will be requested from the offeror during the negotiation process. The initial proposal need only indicate from what source the proposed costs and prices are substantiated.]

(3) **Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data** [FAR Clause 52.215-20 (October 1997)]

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

Alternate I (October 1997). As prescribed in 15.408(l), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

(b)(1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

(4) **Total Compensation Plan - Instructions**

[NOTE: This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.a. of this RFP.]

a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors [included in the competitive range will be required to/as a part of their business proposal] will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

(5) **Total Compensation Plan - Evaluation**

a) **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must

recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

b) **Cost (Professional Compensation)**

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

c) **Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

d) **Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

(6) **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

Performance history is defined as meeting contract objectives within delivery and cost schedules on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts,

separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(7) **Other Administrative Data**

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

c) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38,** (May 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).

(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

d) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

e) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

f) **Facilities Capital Cost of Money**, FAR 52.215-16, (June 2003)

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(8) **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:
http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

(9) **Proposer's Annual Financial Report**

[NOTE: This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.a. of this RFP.]

All offerors included in the competitive range will be required to submit a copy of the organization's most recent annual financial report.

(10)**Representations and Certifications**

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(11)**Travel Costs/Travel Policy**

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

[NOTE: This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.a. of this RFP.]

All offerors included within the competitive range will be required to submit one copy of their written travel policy. A written travel policy for any proposed subcontractors shall also be

submitted at that time. If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

a. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, and past performance. Although technical factors are of paramount consideration in the award of the contract, past performance and cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

b. MANDATORY QUALIFICATION CRITERIA

Listed below are mandatory qualification criteria. The offeror shall include all information which documents and/or supports the qualification criteria in one clearly marked section of its proposal. The qualification criteria establishes conditions that must be met at the time of receipt of Final Proposal Revisions (FPRs) by the Contracting Officer in order for your proposal to be considered any further for award.

The contractor must be able to attend meetings at the NIH in Bethesda, Maryland, within 2 hours of notification of the required meeting.

c. EVALUATION OF OPTIONS

It is anticipated that any contract awarded from this solicitation will contain option provisions and periods. In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

d. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

CRITERIA		WEIGHT
I. Understanding of the purpose and need for this project, completeness of the plan presented to indicate understanding of the Statement of Work, and feasibility of the approach and methods proposed.		**50%**
a. Demonstrated knowledge about data safety monitoring and scientific advisory boards including the functions and responsibilities of these boards, and the logistical and professional support needed.	25%	

b. Demonstrated knowledge and experience in providing assistance to principal investigators in the conduct of clinical research and the development of plans for assessments of and assistance to clinical studies including clinical trials. 15%

c. Demonstrated knowledge of NIH and FDA regulations and policies regarding clinical studies and the protection of human subjects which may require the development or updating of current NIAMS clinical research guidelines or training module. 10%

II. **PERSONNEL** - Qualifications of personnel and relevance of staff background in terms of professional credentials and expertise. Qualifying backgrounds include expertise in statistics/clinical trials methodology, data coordinating experience, and secretarial/clerical capabilities **35%**

a. The Project Director should have a relevant, professional degree (PhD or its equivalent or Masters level degree with15 years experience in conducting clinical trials), and must have prior experience (at least 10 years) and demonstrated ability in statistics/clinical trials methodology with data coordinating experience and participated in data safety monitoring activities. He/she must have the ability to provide consultation to principal investigators and other staff involved in the study being assessed. He/she must have the ability to recruit physician consultants in the specialties for which the clinical trials are being conducted, for example, rheumatologists, dermatologists, endocrinologists, and other experts appropriate to the studies. Various areas of expertise will be needed throughout the duration of the contract. 10%

b. The Project Coordinator shall have a Masters in Public Health or its equivalent or 10 years experience, and demonstrated ability in the conduct of clinical trials. 10%

c. The statistician shall have appropriate credentials (a Ph.D. or its equivalent or 10 years participating as a clinical trial statistician), prior experience and demonstrated ability in the conduct of clinical trials including epidemiological studies and in the generation of statistical reports to data safety monitoring boards. 5%

d. The computer specialist shall have demonstrated experience and technical skills with database and website design, development, and maintenance. Personnel should have experience converting text and graphical documents for the Web. Personnel should have extensive knowledge of the software, hardware, programming, logistics, and technical ability needed to maintain and manipulate data efficiently. 10%

III. **COMMUNICATIONS** - The offeror shall demonstrate evidence of their capability to be skillful and responsive in communication and interaction with NIAMS staff and clinical site personnel involved in the various clinical trials. **10%**

IV. **FACILITIES** - Adequacy of equipment and facilities. Standard, compatible computer **5%**

equipment with capabilities for communicating electronically with NIAMS staff and clinical trial investigators is required. Software utilized by NIAMS includes WORD, WordPerfect, and Excel. Facilities with adequate storage space for maintaining documents, records, and/or reports related to the assessments should be available. The offeror shall demonstrate the ability to manage staff in order to address perturbation in work load and the provision of back up personnel.

TOTAL **100%**

e. **PAST PERFORMANCE FACTOR**

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the competitive range on the basis of the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgement by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP

The following pages include Attachments applicable to this RFP as specified in SECTION J - List of Attachments.

PACKAGING AND DELIVERY OF THE PROPOSAL

EXTERNAL PACKAGE MARKING

In addition to the address cited below, mark each package as follows:

"RFP NO. NIH-NIAMS-06-01

TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

PLEASE READ THE FOLLOWING INFORMATION CAREFULLY:

NUMBER OF COPIES

TECHNICAL PROPOSAL: ORIGINAL* AND 10 COPIES

BUSINESS PROPOSAL: ORIGINAL* AND 4 COPIES

If hand-delivered or delivery service

BDR\NIAMS Contracts Branch
Office of Acquisitions, Division of Extramural Affairs
National Heart, Lung and Blood Institute, NIH
One Democracy Plaza
6701 Democracy Blvd., Suite 800, MSC 4872
Bethesda, Maryland 20817-4872
Telephone: 301-594-2543
FAX: 301-480-5996

If using U.S. Postal Service

BDR\NIAMS Contracts Branch
Office of Acquisitions, Division of Extramural Affairs
National Heart, Lung and Blood Institute, NIH
One Democracy Plaza
6701 Democracy Blvd., Suite 800, MSC 4872
Bethesda, Maryland 20892-4872
Telephone: 301-594-2543
FAX: 301-480-5996

*THE ORIGINALS MUST BE READILY ACCESSIBLE FOR DATE STAMPING PURPOSES.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the Rockville, Maryland address. Any package sent to the Rockville address via this service will be held at a local post office for pick-up. The Government is not responsible for picking up any mail at a local post office. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal."

PROPOSAL INTENT RESPONSE SHEET

RFP No.: **NIH-NIAMS-06-01**

TITLE: **ASSESSMENT AND ASSISTANCE FOR NIAMS CLINICAL STUDIES**

PLEASE REVIEW THE REQUEST FOR PROPOSALS. FURNISH THE INFORMATION REQUESTED BELOW AND RETURN THIS PAGE BY THE EARLIEST PRACTICABLE DATE. YOUR EXPRESSION OF INTENT IS NOT BINDING BUT WILL GREATLY ASSIST US IN PLANNING FOR PROPOSAL EVALUATION.

[ ] DO INTEND TO SUBMIT A PROPOSAL

[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

COMPANY/INSTITUTION NAME:

ADDRESS:

PROJECT DIRECTOR'S NAME:

TITLE:

TELEPHONE NUMBER:

E-MAIL ADDRESS:

NAMES OF COLLABORATING INSTITUTIONS AND INVESTIGATORS
(include Subcontractors and Consultants):

AUTHORIZED SIGNATURE:

TYPED NAME AND TITLE:

DATE:

RETURN BY NO LATER THAN JANUARY 26, 2006 TO:

Lisa Hill
Contracting Officer
BDR/NIAMS Contracts Branch, OA, DEA
National Heart, Lung and Blood Institute, NIH
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6701 Democracy Boulevard, Suite 800, MSC 4872
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